Drug Manufacturing

(SIC 283)

SIGNIFICANT POINTS

- Half of all workers have a bachelor's, master's, professional, or Ph.D. degree—roughly double the proportion for all industries combined.
- More than 40 percent of all jobs are in large establishments employing more than 1,000 workers.
- Drug manufacturing ranks among the faster growing manufacturing industries.
- Earnings are much higher than those in other manufacturing industries.

Nature of the Industry

The drug manufacturing industry has produced a variety of medicinal and other health-related products undreamed of by even the most imaginative apothecaries of the past. These drugs save the lives of millions of people from various diseases and permit many ill people to lead normal lives.

Thousands of medications are available today for diagnostic, preventive, and therapeutic uses. In addition to aiding in the treatment of infectious diseases such as pneumonia, tuberculosis, malaria, influenza, and sexually transmitted diseases, these medicines also help prevent and treat cardiovascular disease, asthma, diabetes, and cancer. For example, anti-nausea drugs help cancer patients endure chemotherapy; clot-buster drugs help stroke patients avoid brain damage; and psychoactive drugs reduce the severity of mental illness for many people. Antibiotics and vaccines have virtually wiped out such diseases as diphtheria, syphilis, and whooping cough. Discoveries in veterinary drugs have increased animal productivity and controlled various diseases, some of which are transmissible to humans.

At each stage of life—from early infancy through old age—innovative drug discoveries help millions of patients lead longer, healthier, happier, and more productive lives. These longer life spans are due, in large part, to the conquest of diseases by drug research and manufacturing. But modern drugs do even more than save lives and improve the well-being of patients. As they improve health, they also save money by keeping people out of hospitals, emergency rooms, and nursing homes.

Advances in biotechnology and information technology are transforming drug discovery and development. Within biotechnology, scientists have learned a great deal about human genes, but the real work—translating that knowledge into viable new drugs—is just beginning. Thousands of new drugs are expected to be developed in the coming years.

There is a direct relationship between gene discovery and identification of new drugs: the more genes identified, the more paths available for drug discovery. Discovery of new genes also can lead to new diagnostics for the early detection of disease. Among other uses, new genetic technology is being explored to develop vaccines to prevent or treat diseases that have eluded traditional vaccines, such as AIDS, malaria, tuberculosis, and cervical cancer.

The drug industry consists of more than 2,500 places of employment, located throughout the country. These include establishments that make pharmaceutical preparations or finished

drugs; biological products, such as serums and vaccines; bulk chemicals and botanicals used in making finished drugs; and diagnostic substances such as pregnancy and blood glucose kits. Pharmaceutical manufacturing firms make up the majority of establishments and employ almost 80 percent of the workers in this industry.

The U.S. drug industry has achieved worldwide prominence through research and development (R&D) of new drugs, and spends a relatively high proportion of its funds on R&D compared with other industries. Each year, drug industry testing involves many thousands of new substances, yet may eventually yield only 10 to 20 new prescription medicines.

For the majority of firms in this industry, the actual manufacture of drugs is the last stage in a lengthy process that begins with scientific research to discover new products and to improve or modify existing ones. The R&D departments in drug manufacturing firms start this process by seeking new chemical compounds with the potential to prevent, combat, or alleviate symptoms of diseases or other health problems. Scientists use sophisticated tools, such as computer simulation and combinatorial chemistry, to hasten and simplify the discovery of potentially useful new compounds.

Most firms devote a substantial portion of their R&D budgets to applied research, using scientific knowledge to develop a drug targeted to a specific use. For example, an R&D unit may focus on developing a compound that will effectively slow the advance of breast cancer. If the discovery phase yields promising compounds, technical teams then attempt to develop a safe and effective product based on the discoveries.

To test new products in development, a research method called "screening" is used. To screen an antibiotic, for example, a sample is first placed in a bacterial culture. If the antibiotic is effective, it is next tested on infected laboratory animals. Laboratory animals also are used to study the safety and efficacy of the new drug. A new drug is selected for testing in humans only if it promises to have therapeutic advantages over drugs already in use, or is safer. Drug screening is an incredibly risky, laborious, and high-cost process—only one in every 5,000 to 10,000 compounds screened eventually becomes an approved drug.

After laboratory screening, firms conduct clinical investigations, or "trials," of the drug on human patients. Human clinical trials normally take place in three phases. First, medical scientists administer the drug to a small group of healthy volunteers to determine and adjust dosage levels, and monitor for side effects. If a drug appears useful and safe, additional tests are conducted in two more phases, each phase using a successively larger group of volunteers or carefully selected patients.

After a drug successfully passes animal and clinical tests, the U.S. Food and Drug Administration (FDA) must review the drug's performance on human patients before approving the substance for commercial use. The entire process, from the first discovery of a promising new compound to FDA approval, can take many years. However, scientific and information technology advances will shorten that process considerably for most drugs. Furthermore, the FDA is becoming more efficient in reviewing and approving drugs.

After FDA approval, problems of production methods and costs must be worked out before manufacturing begins. If the original laboratory process of preparing and compounding the ingredients is complex and too expensive, pharmacists, chemists, chemical engineers, packaging engineers, and production specialists are assigned to develop a manufacturing process economically adaptable to mass production. After marketing the drug, new production methods may be developed to incorporate new technology or to transfer the manufacturing operation to a new production site.

In many production operations, drug manufacturers have developed a high degree of automation. Milling and micronizing machines, which pulverize substances into extremely fine particles, are used to reduce bulk chemicals to the required size. These finished chemicals are combined and processed further in mixing machines. The mixed ingredients may then be mechanically capsulated, pressed into tablets, or made into solutions. One type of machine, for example, automatically fills, seals, and stamps capsules. Other machines fill bottles with capsules, tablets, or liquids, and seal, label, and package the bottles.

Quality control and quality assurance are vital in this industry. Many production workers are assigned full time to quality control and quality assurance functions, whereas other employees may devote part of their time to these functions. For example, although pharmaceutical company sales representatives, often called detailers, primarily work in marketing, they engage in quality control when they assist pharmacists in checking for outdated products.

Working Conditions

Working conditions in drug plants are better than in most other manufacturing plants. Much emphasis is placed on keeping equipment and work areas clean because of the danger of contamination. Plants usually are air-conditioned, well lighted, and quiet. Ventilation systems protect workers from dust, fumes, and disagreeable odors. Special precautions are taken to protect the relatively small number of employees who work with infectious cultures and poisonous chemicals. With the exception of work performed by material handlers and maintenance workers, most jobs require little physical effort. In 1999, the incidence of work-related injury and illness was 3.8 cases per 100 full-time workers, compared with 9.2 per 100 for all manufacturing industries and 6.3 per 100 for the entire private sector.

Only 4.6 percent of the workers in the drug manufacturing industry are union members or are covered by a union contract, compared with 14.9 percent of workers throughout private industry.

Employment

Drug manufacturing provided 315,000 wage and salary jobs in 2000. Almost 8 out of 10 jobs were in establishments that

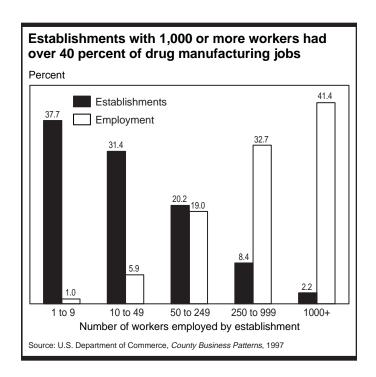
made pharmaceutical preparations or finished drugs, such as tranquilizers, antiseptics, and antibiotics. The remaining jobs were in establishments that made biological products, such as serums and vaccines; bulk medicinal chemicals and botanicals used in making finished drugs; or diagnostic substances such as pregnancy and glucose tests.

Drug manufacturing establishments typically employ many workers. More than 40 percent of this industry's employees work for firms with more than 1,000 workers (chart). Most jobs are in California, Illinois, Indiana, New Jersey, New York, North Carolina, and Pennsylvania.

Occupations in the Industry

About 22 percent of all jobs in the drug manufacturing industry are in professional and related occupations, mostly scientists and science technicians, and about 29 percent are in managerial, administrative support, and sales occupations. Almost half of the jobs in the drug manufacturing industry are in production, maintenance, or material-moving occupations, including both low-skilled and high-skilled jobs (table 1).

Scientists, engineers, and technicians conduct research to develop new drugs. Others work to streamline production methods and improve environmental and quality control. Life scientists are among the largest scientific occupations in this industry. Most of these scientists are biological and medical scientists who produce new drugs using biotechnology to recombine the genetic material of animals or plants. Biological scientists normally specialize in a particular area. Biologists and bacteriologists study the effect of chemical agents on infected animals. Biochemists study the action of drugs on body processes by analyzing the chemical combination and reactions involved in metabolism, reproduction, and heredity. Microbiologists grow strains of microorganisms that produce antibiotics. Physiologists investigate the effect of drugs on body functions and vital processes. Pharmacologists and zoologists study the effect of drugs on animals. Virologists grow viruses, and develop vaccines and test them in animals. *Botanists*, with their special knowledge of plant life, contribute to the discovery of



botanical ingredients for drugs. Other biological scientists include pathologists, who study normal and abnormal cells or tissues, and toxicologists, who are concerned with the safety, dosage levels, and compatibility of different drugs. Medical scientists, who also may be physicians, conduct clinical research, test products, and oversee human clinical trials.

Physical scientists, particularly *chemists*, also are important in the research and development of new drugs. Organic chemists combine new compounds for biological testing. Physical chemists separate and identify substances, determine molecular structure, help create new compounds, and improve manufacturing processes. Radiochemists trace the course of drugs through body organs and tissues. Pharmaceutical chemists set standards and specifications for the form of products and for storage conditions; they also see that drug labeling and literature meet the requirements of State and Federal laws. Analytical chemists test raw and intermediate materials and finished products for quality.

Science technicians, such as biological and chemical technicians, play an important part in research and development of new medicines. They set up, operate, and maintain laboratory equipment, monitor experiments, analyze data, and record and interpret results. Science technicians usually work under the supervision of scientists or engineers.

Although engineers account for a small fraction of scientific and technical workers, they make significant contributions toward improving quality control and production efficiency. Chemical engineers design equipment and devise manufacturing processes. Bioprocess engineers, who are similar to chemical engineers, design fermentation vats and various bioreactors for microorganisms that will produce a given product. *Indus*trial engineers plan equipment layout and workflow to maintain efficient use of plant facilities.

At the top of the managerial group are executives who make policy decisions concerning matters of finance, marketing, and research. Other managerial workers include natural sciences managers and industrial production managers.

Office and administrative support employees include secretaries, general office clerks, and others who keep records on personnel, payroll, raw materials, sales, and shipments.

Pharmaceutical sales representatives, often called pharmaceutical detailers, describe their company's products to physicians, pharmacists, dentists, and health services administrators. These sales representatives serve as lines of communication between their companies and clients.

Most plant workers fall into one of three occupational groups: production or processing workers who operate drug-producing equipment and inspect products; maintenance workers who install, maintain, and repair production equipment; and transportation and material-moving workers who package and transport the drugs.

Workers in the largest of the production occupations, team assemblers, perform all of the assembly tasks assigned to their teams, rotating through the different tasks, rather than specializing in a single task. They also may decide how the work is to be assigned and how different tasks are to be performed.

Other workers specialize in one part of the production process. Chemical processing machine setters, operators, and tenders, such as pharmaceutical operators control machines that produce tablets, capsules, ointments, and medical solutions. Mixing and blending machine setters, operators, and tenders, such as granulator machine operators tend milling and

Table 1. Employment of wage and salary workers in drug manufacturing by occupation, 2000 and projected change, 2000-10. (Employment in thousands)

	Employment, 2000		
Occupation Num	ber	Percent	2010
All occupations Management, business, and financial	315	100.0	23.8
occupations Marketing and sales managers General and operations managers Industrial production managers Natural sciences managers	41 3 4 5 3	13.1 1.0 1.2 1.6 0.8	25.2 42.5 22.4 20.5 18.0
Accountants and auditors	2	0.8	29.6
Professional and related occupations Computer specialists Chemical engineers Industrial engineers, including health	70 6 3	22.3 1.8 0.9	33.0 59.8 23.9
and safety Drafters, engineering, and mapping	-		
technicians Biological scientists Medical scientists Chemists Biological technicians Chemical technicians Healthcare practitioners aand technical occupations	4 11 3 14 7 8	1.3 3.4 1.0 4.6 2.1 2.5	20.6 29.6 42.5 42.5 26.7 29.6
Service occupations	7	2.1	26.0
Janitors and cleaners, except maids and housekeeping cleaners	4	1.2	29.6
Sales and related occupations Sales representatives, wholesale and manufacturing, technical and scientific products	6	1.8	18.5 16.6
Office and administrative support occupations Bookkeeping, accounting, and auditing	43	13.7	15.2
clerks Customer service representatives Shipping, receiving, and traffic clerks Office clerks, general Secretaries, except legal, medical, and	4 4 6 3	1.2 1.1 1.8 1.1	11.6 26.9 18.7 23.7
executive Construction and extraction	3	1.1	3.7
Construction trades and related	3	1.1 1.0	32.5 32.9
workers Installation, maintenance, and repair		1.0	34.3
occupations Industrial machinery mechanics	17 3	5.4 1.1	20.6 29.6
Production occupations		37.4	21.1
production and operating workers Team assemblers Chemical plant and system operators Chemical processing machine setters,	11 33 3	3.4 10.6 0.8	16.6 16.6 29.6
operators, and tenders Mixing and blending machine setters,	9	2.9	39.5
operators, and tenders	8	2.6	29.6
and weighersPackaging and filling machine operators	11	3.6	3.7
and tenders Transportation and material moving	19	6.1	29.6
occupations Packers and packagers, hand	9 3	3.0 0.9	24.5 29.6

NOTE: May not add to totals due to omission of occupations with small employment.

grinding machines that reduce mixtures to particles of designated sizes. Compounders tend tanks and kettles in which solutions are mixed and compounded to make up creams, ointments, liquid medications, and powders. Compressors operate machines that compress ingredients into tablets. Pill and tablet coaters, often called capsule coaters, control a battery of machines that apply coatings that flavor, color, preserve, or add medication to tablets, or control disintegration time. Ampoule fillers operate machines that fill small glass containers with measured doses of liquid drug products. Throughout the production process, inspectors, testers, sorters, samplers, and weighers ensure consistency and quality. For example, ampoule examiners examine ampoules for discoloration, foreign particles, and flaws in the glass. *Tablet testers* inspect tablets for hardness, chipping, and weight to assure conformity with specifications.

After the drug is prepared and inspected, it is bottled or otherwise packaged by *packaging and filling machine operators and tenders*. Semi-skilled workers do most of the packaging and bottle-filling with machines that measure exact amounts of the product and seal containers.

Plant workers who do not operate or maintain equipment perform a variety of other tasks. Some drive industrial trucks or tractors to move materials around the plant, load and unload trucks and railroad cars, or package products and materials by hand.

Training and Advancement

Training requirements for jobs in the drug industry range from a few hours of on-the-job training to years of formal education plus job experience. About half of all workers have a bachelor's or graduate degree—roughly double the proportion for all industries combined. The drug industry places a heavy emphasis on continuing education for employees, and many firms provide classroom training in safety, environmental and quality control, and technological advances.

For production and maintenance occupations, drug manufacturers usually hire inexperienced workers and train them on the job; high school graduates are generally preferred. Beginners in production jobs assist experienced workers and learn to operate processing equipment. With experience, employees may advance to more skilled jobs in their departments.

Many companies encourage production and maintenance workers to take courses related to their jobs in local schools and technical institutes or to enroll in correspondence courses. College courses in chemistry and related areas are particularly encouraged for highly skilled production workers who operate sophisticated equipment. Some companies reimburse workers for part, or all, of their tuition. Skilled production and maintenance workers with leadership ability may advance to supervisory positions.

For science technicians in the drug industry, most companies prefer to hire graduates of technical institutes or junior colleges or those who have completed college courses in chemistry, biology, mathematics, or engineering. Some companies, however, require science technicians to hold a bachelor's degree in a biological or chemical science. In many firms, newly hired workers begin as laboratory helpers or aides, performing routine jobs, such as cleaning and arranging bottles, test tubes, and other equipment.

The experience required for higher level technician jobs varies from company to company. Usually, employees advance

over a number of years from assistant technician, to technician, to senior technician, and then to technical associate, or supervisory technician.

For most scientific and engineering jobs, a bachelor of science degree is the minimum requirement. Scientists involved in research and development usually have a master's or doctoral degree. A doctoral degree is generally the minimum requirement for medical scientists, and those who administer drug or gene therapy to patients in clinical trials must have a medical degree. Because biotechnology is not one discipline, but the interaction of several disciplines, the best preparation for work in biotechnology is training in a traditional biological science, such as genetics, molecular biology, biochemistry, virology, or biochemical engineering. Individuals with a scientific background and several years of industrial experience may eventually advance to managerial positions. Some companies offer training programs to help scientists and engineers keep abreast of new developments in their fields and to develop administrative skills. These programs may include meetings and seminars with consultants from various fields. Many companies encourage scientists and engineers to further their education; some companies provide financial assistance or full reimbursement for this purpose. Publication of scientific papers also is encouraged.

Drug manufacturing companies prefer to hire college graduates, particularly those with strong scientific backgrounds, as pharmaceutical detailers. Newly employed pharmaceutical representatives complete rigorous formal training programs revolving around their company's product lines.

Earnings

Earnings of workers in the drug industry are higher than the average for all manufacturing industries. In 2000, production or nonsupervisory workers in the drug industry averaged \$766 a week, while those in all manufacturing industries averaged \$597 a week. Earnings in selected occupations in drug manufacturing appear in table 2.

Some employees work in plants that operate around the clock—three shifts a day, 7 days a week. In most plants, workers receive extra pay when assigned to the second or third shift. Because drug production is subject to little seasonal variation, work is steady.

Table 2. Median hourly earnings of the largest occupations in drug manufacturing, 2000.

Occupation	Drug manufacturing	All industries
Industrial production managers	. \$ 36.32	\$ 29.64
Chemists	. 24.43	24.07
First-line supervisors/managers of		
production and operating workers	. 23.44	19.39
Industrial machinery mechanics	. 19.79	17.30
Maintenance and repair workers,		
general	. 18.55	13.39
Chemical technicians		17.05
Chemical equipment operators and		
tenders	. 16.91	17.21
Biological technicians	. 16.78	15.16
Inspectors, testers, sorters, samplers,		
and weighers	. 14.11	12.22
Team assemblers		10.32

Outlook

Wage and salary jobs in drug manufacturing are expected to increase by about 24 percent over the 2000-10 period, compared with 16 percent for all industries combined. Drug manufacturing ranks among the faster growing manufacturing industries. Demand for this industry's products is expected to remain strong. Even during fluctuating economic conditions, there will be a market for over-the-counter and prescription drugs, including the diagnostics used in hospitals, laboratories, and homes; the vaccines used routinely on infants and children; analgesics and other symptom-easing drugs; and antibiotics and "miracle" drugs for life-threatening diseases.

Although the use of drugs, particularly antibiotics and vaccines, has helped eradicate or limit a number of deadly diseases, many others, such as cancer, Alzheimer's, and heart disease, continue to elude cures. Ongoing research and the manufacture of new products to combat these diseases will continue to contribute to employment growth.

Because so many of the drug industry's products are related to preventive or routine health care, rather than just illness, demand is expected to increase as the population expands. The growing number of older people who will require more health care services will further stimulate demand—along with the growth of both public and private health insurance programs, which increasingly cover the cost of drugs and medicines.

Another factor propelling demand is the increasing popularity of lifestyle drugs—drugs that are not necessarily vital to one's well being, but help enhance self-confidence or physical appearance. Other factors expected to increase the demand for drugs include a more industry-friendly regulatory environment that has streamlined the FDA approval process, a healthy pipeline of potential new drugs, greater personal income, and the rising health consciousness and expectations of the general public.

Despite the increasing demand for drugs, drug producers and buyers are expected to place more emphasis on cost-effectiveness, due to concerns about the cost of healthcare, including prescription drugs. Growing competition from the producers of generic drugs also may exert cost pressures on many firms in this industry. These factors, combined with continuing improvements in manufacturing processes, are expected to result in slower employment growth over the 2000-10 period than occurred during the previous 10-year period.

Faster-than-average growth is anticipated for professional occupations—especially the biological and medical scientists

engaged in research and development, the backbone of the drug industry, and computer specialists such as systems analysts and computer support specialists. Faster-than-average growth also is projected for production occupations. Employment of office and administrative support workers is expected to experience average growth, as companies streamline operations and increasingly rely on computers. In an effort to streamline research and technological development costs, some drug companies have merged. As companies consolidate and grow in size, so do their marketing and sales departments. Drug firms have dramatically increased their pharmaceutical sales forces over the past several years, and this trend is likely to continue.

Unlike many other manufacturing industries, the drug industry is not highly sensitive to changes in economic conditions. Even during periods of high unemployment, work is likely to be relatively stable in this industry.

Sources of Additional Information

For additional information about careers in drug manufacturing and the industry in general, write to the personnel departments of individual drug manufacturing companies.

For information about careers in biotechnology, contact:

Biotechnology Industry Organization, Suite 1100, 1625 K St. NW., Washington, DC 20006. Internet: http://www.bio.org

For information on careers in drug manufacturing, contact:

Pharmaceutical Research and Manufacturers of America (PHRMA), 1100 15th St. NW., Washington, DC 20005. Internet: http://www.phrma.org

Information on these key drug-manufacturing occupations may be found in the 2002-03 edition of the *Occupational Outlook Handbook*.

- Assemblers and fabricators
- Biological and medical scientists
- Chemists and materials scientists
- Engineers
- Inspectors, testers, sorters, samplers, and weighers
- Sales representatives, wholesale and manufacturing
- Science technicians
- Systems analysts, computer scientists, and database administrators